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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/399,083	09/17/1999	DAVID CALDERWOOD	BBIC-043/A	1842

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EXAMINER
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RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/399,083

Applicant(s)

CALDERWOOD ET AL.

Examiner

Deepak Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 November 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 10, 11 and 46-52 ☒ are pending in the application.
- 4a) Of the above claim(s) 11 and 48-51 ☒ are withdrawn from consideration.
- 5) ☒ Claim(s) 52 is/~~are~~ allowed.
- 6) ☒ Claim(s) 1-8, 10, 46-47 ☒ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

This office action is in response to the amendment filed on November 30, 2004.

Claims 1-8, 10-11 and 46-52 are pending in this application.

#### ***Election/Restrictions***

Applicant is reminded that the examination is based on the elected species (as indicated in previous office actions) which reads on claims 1-8, 10, 46, 47 and 52.

Claims 11 and 48-51 are withdrawn from further consideration as being drawn to nonelected species (see MPEP §803.02) pursuant to 37 CFR 1.142(b).

Claims 1-8, 10, 46, 47 and 52 are considered to the extent readable on the examined subgenus, i.e., structural formula of claim 1 wherein ring A is phenyl; L is -NH-SO<sub>2</sub>-; j is 0; R<sub>3</sub> is substituted phenyl; R<sub>2</sub> is H; and R<sub>1</sub> is cyclopentyl, and **all** other definitions of the variables and the other species are withdrawn from consideration as being drawn to nonelected species.

#### ***Withdrawn Rejections/Objections:***

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

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***The following rejections are maintained:***

1. Claims 1-8, 10 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

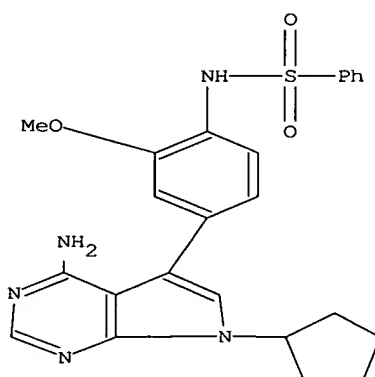
In claim 1, in the definition of  $R_c$ , the recitation “-W-(CH<sub>2</sub>)<sub>t</sub>-NR<sub>d</sub>R<sub>e</sub>” is repeated (see page 3, lines 9 and 10). This was indicated in the previous office action, however, the claims continues to contain the duplicate recitation. Deletion of one of the occurrences is suggested.

2. Claims 1-8, 10, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calderwood et al., WO 98/41525. The reference teaches a generic group of compounds which embraces applicant's instantly claimed compounds. See formula I in page 2 wherein  $R_3$  is represented by formula (a) wherein the phenyl ring of formula (a) is optionally further substituted (see page 3, lines 6-9); A is NHSO<sub>2</sub> (page 3, line 10) and  $R_5$  is optionally substituted phenyl. The reference further discloses several species that fall within the above genus, see pages 10-14, particularly page 14, lines 9-14 and 22-23. The compounds are taught to be useful as pharmaceutical therapeutic agents having protein kinase inhibition activity, see the entire document. Applicant excluded the specific compounds disclosed in the reference by a proviso statement. The claims however, continue to encompass compounds within reference genus. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole

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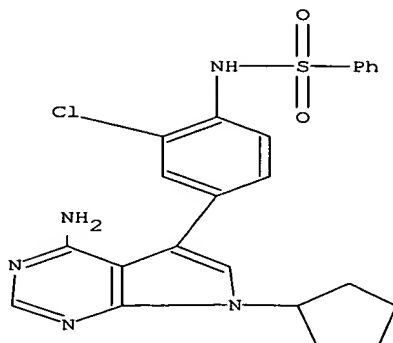
i.e., as pharmaceutical therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render *prima facie* obvious a species falling within a genus.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that a *prima facie* case of obviousness has not been established because the reference does not provide any suggestion or motivation to modify the reference compounds to arrive at claimed compounds. This is not found to be persuasive because the reference clearly teaches 4-amino-7H-pyrrolo[2,3-d]pyrimidin-5-yl compounds having an optionally substituted phenyl ring (wherein the optional substituents include alkoxy, halo, etc. see the list in page 3, lines 26-28) attached at the 5-position, which phenyl is further substituted with -A-R<sub>5</sub>. The reference also discloses a species falling within the above genus, see e.g., the compound of Example 34 which is depicted below for convenience:



Claim 46 of the instant application includes the species N-(4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-chlorophenyl)-1-benzenesulfonamide (lines 12-13) which is depicted below for convenience:

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As can be seen from the above two structural formula, the only difference between the reference compound and the instantly claimed compound is the optional substituent at the 2-position. The reference discloses a methoxy substituent and further teaches the equivalency of alkoxy, halogen, etc. as all these are taught to be alternatives as substituents on the phenyl ring. Therefore, the reference clearly suggests the instantly claimed compounds. Further, both the reference compounds as well as the instantly claimed compounds are disclosed to be useful as tyrosine kinase inhibitors.

Applicant cites *Stratoflex, Inc. v. Aeroquip Corp.* (218 USPQ 871) and *Schenck v. Nortron Corp.* (218 USPQ 698) and argues that 'in order to make a prima facie case of obviousness, the invention as a whole must be considered'. The case laws cited by applicant have been fully considered, however, it is maintained that the reference fairly suggests the instantly claimed compounds to one of ordinary skill in the art. It is to be noted that rejection under 35 U.S.C. 103 is proper where the subject matter claimed "is not *identically* disclosed or described" in the prior art, and the prior art directs those skilled in the art to the compounds, without any need for picking, choosing, and combining various disclosures. See *In re Shaumann et al.*, 572 F.2d 312, 315, 316, 197 USPQ 5, 8, (CCPA 1978). Further, the reference teaches that the compounds are useful as pharmaceutical agents, which is sufficient to one of

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ordinary skill to make the claimed compounds because similar properties are normally presumed when compounds are very close in structure. Where the specific compound falls within the ambit of a “very limited number of compounds”, the fact that a specific embodiment is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered.” *In re Lamberti*, 545 F.2d 747,750, 192 USPQ 278, 280 (CCPA 1976). “The question under 35 U.S.C. 103 is not merely what the reference expressly teaches but what it would have suggested to one of ordinary skill in the art at the time the invention was made.”

“Structural relationships provide the requisite motivation or suggestion to modify known compounds to obtain new compounds.” See *In re Duel*, 51 F.3d at 1558, 34 USPQ2d at 1214. The closer the physical and chemical similarities between the claimed species or subgenus and any exemplary species or subgenus disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner to the genus. See *In re Dillon*, 919 F.2d at 696, 16 USPQ2d at 1904. “An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.” *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). Reference must be considered, under 35 U.S.C. 103, not only for what it expressly teaches but also for what it fairly suggests; all disclosures of prior art, including unpreferred embodiments, must be considered in determining obviousness. *In re Burckel*, 201 USPQ 67 (CCPA 1979).

For all the above reasons, the rejection is maintained.

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***Duplicate Claims***

Applicant is advised that should claim 6 be found allowable, claim 7 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 7 does not further limit the scope of claim 6.

***Allowable Subject Matter***

Claim 52 is allowed. (The reasons provided in the previous office action are incorporated here by reference).

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.




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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Deepak Rao  
Primary Examiner  
Art Unit 1624

February 17, 2005